

REMARKS

Claims 1, 4-18, 84, 97-98, 100-108, 110-117, 119-128, 130-132, 134-137, 139-141, 143-218, 220-221, and 224 were pending in this application at the time of the Office Action dated January 7, 2009. Claims 1, 5-14, 84, 97-98, 100-101, 103-107, 128, 130-132, 134-137, 139-141, 148, 152-153, 182-183, 189-190, 196-197, 203-204, 206-207, 209-211, and 217-218 were under examination and claims 4, 15-18, 102, 108, 110-117, 119-127, 143-147, 149-151, 154-181, 184-188, 191-195, 198-202, 205, 208, 212-216, 220-221, and 224 were withdrawn from consideration. Claims 119, 130, and 139 have been amended. Accordingly, claims 1, 5-14, 84, 97-98, 100-101, 103-107, 128, 130-132, 134-137, 139-141, 148, 152-153, 182-183, 189-190, 196-197, 203-204, 206-207, 209-211, and 217-218 are now pending and under examination.

Amendments

Claims 119, 130, and 139 have been amended to now depend from claim 117, 128, and 137, respectively. No new matter has been added.

With respect to the amendment of claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicant expressly reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

35 U.S.C. § 103

Claims 1, 5-14, 84, 97-98, 100-101, 103-107, 128, 130-132, 134-137, 139-141, 148, 152-153, 182-183, 198-190, 196-197, 203-204, 206-207, 209-211 and 217-218 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Desai et al. (WO 00/71079) in view of Gelfand et al. (EP 0227593) and further in view of Flournoy (*Eur J Clin Microbiol Infect Dis* 10(7):597-598 (1991)).

The Examiner alleges that it would have been obvious to one of ordinary skill in the art to modify the teaching of Desai et al. by further incorporating the deferoxamine of Gelfand et al. and Flournoy into the human serum albumin:paclitaxel compositions. The Examiner states that the

motivation to do so is given by Desai et al., which suggest that pharmacological active agents (i.e. antineoplastics, antimicrobials, etc.), can be combined into a composition with an albumin carrier and Gelfand et al. and Flournoy. Gelfand et al. is cited as allegedly disclosing that deferoxamine is an iron chelator that has a synergistic effect when used with antineoplastic drugs, while Flournoy is cited as allegedly disclosing that deferoxamine has antimicrobial properties.

Applicants respectfully disagree. Applicants submit that there is no motivation to modify the teach of Desai et al. by further incorporating the deferoxamine of Gelfand et al. and Flournoy into the human serum albumin:paclitaxel composition. As the Examiner states, Desai et al. do not teach a composition which comprises both paclitaxel and an antimicrobial agent. Desai et al. provides a list of substantially water insoluble pharmacologically active agents, such as antineoplastics and antimicrobials, which can be used as the pharmaceutical active agent. Desai et al. at page 24, line 10 – page 30, line 25. Desai et al. do not teach or suggest the use of an antimicrobial agent (*e.g.*, deferoxamine) to inhibit microbial growth in a pharmaceutical composition.

Further, there is no teaching or suggestion in Gelfand et al. to combine paclitaxel with deferoxamine. Paclitaxel is not even mentioned in the disclosure of Gelfand et al. Further, as noted by the Examiner, Gelfand et al. do not teach that deferoxamine has antimicrobial properties. Gelfand et al. teach the use of iron chelating agents, particularly deferoxamine, in connection with synergistic treatment of cancer with cytostatically effective preparations. Gelfand et al. at Abstract. Specifically, Gelfand et al. disclose a synergistic growth inhibitory effect using deferoxamine as a pharmaceutical active agent, and various concentrations of daunomycin, vincristine, Ara-C, and methotrexate. Gelfand et al. at page 8, lines 39-41. No taxane, much less paclitaxel, was even tested in Gelfand et al. A person skilled in the art would have no motivation to combine Gelfand et al. with Desai et al. to achieve the claimed and elected pharmaceutical compositions.

Flournoy does not cure the deficiencies of either Desai et al. or Gelfand et al. Flournoy is cited as teaching that deferoxamine mesylate has antimicrobial properties. Flournoy does not teach or suggest a pharmaceutical composition comprising both deferoxamine mesylate and an active agent such as paclitaxel.

Accordingly, none of the references, alone or in combination, teaches or suggests a pharmaceutical composition comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises human serum albumin in an amount effective to reduce one or more side effects of administration of the pharmaceutical agent into a human, and wherein the pharmaceutical composition further comprises deferoxamine in an amount effective to inhibit microbial growth in the pharmaceutical composition as recited in the present claims.

Finally, Applicants note that in the Office Action dated August 25, 2005, claim 84, which has been subsequently narrowed, was considered allowable if written in independent claim format.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 5-14, 84, 97-98, 100-101, 103-107, 128, 130-132, 134-137, 139-141, 148, 152-153, 182-183, 198-190, 196-197, 203-204, 206-207, 209-211, and 217-218 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Desai et al. (WO 00/71079) in view of Gelfand et al. (EP 0227593) and further in view of Flournoy (*Eur J Clin Microbiol Infect Dis* 10(7):597-598 (1991)).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 638772000300. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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